

### **REMARKS**

The Final Office Action mailed September 16, 2010 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1-11, 14-22, and 27 are pending in this application. No amendments are presented herein.

#### **Claim Rejections - 35 U.S.C. § 102**

Claims 1-5, 7-11, 14, 16, 18, 19, and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by USPN 5,156,619 to Ehrenfeld ("Ehrenfeld"). Applicants respectfully traverse this rejection.

In the previous response, Applicants argued that Ehrenfeld fails to show or describe a "generally uniformed surface" as recited in independent claim 1. However, the Examiner has maintained the rejection, alleging that "'generally' is a broad term" and that "'the presence of crimps [does not] necessarily mean[] that any tubular portion shown does not include a 'generally uniform surface' . . . particularly in the absence of any definition . . . for such a claimed term.'" (Office Action, p. 4, emphasis in original.)

Applicants respectfully submit that a definition for "generally uniformed surface" is not required. "The words of a claim must be given their 'plain meaning' unless such meaning is inconsistent with the specification." (MPEP § 2111.01.) Further, "[t]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005) (en banc)." (MPEP § 2111.01.) Accordingly, Applicants submit that a person of ordinary skill in the art at the time of the invention would not interpret the varying surface of the graft of Ehrenfeld as a "generally uniformed surface," at least due to the presence of crimps 34. Although the term "generally uniform surface" envisions *some* amount of deviation from an exactly uniformed

surface,<sup>1</sup> the Ehrenfeld graft with crimps is clearly too varied to be considered “generally uniformed” by a person of ordinary skill in the art at the time of the invention. This is especially true given that the “plurality of crimps 34” extend over the entire Ehrenfeld graft. Applicants reiterate that the presence of crimps *necessarily* means that any tubular portion shown does not include a “generally uniform surface,” as recited in independent claim 1. The crimps cause major variations in the surface of the graft, which leads to a lack of uniformity across the surface.

Further, Applicants have argued that, with respect to the purported disclosure of a first diameter that tapers to a smaller second diameter adjacent the end formation, the cited Ehrenfeld support (col. 1:51-57, col. 2:17-20, col. 2:6-9, FIGS. 1-3) shows and describes the prior art cutting of a graft from a bifurcation and reinforcing the harvested graft with stitches. Nowhere in the Ehrenfeld specification or drawings is there disclosure of a tubular portion having “a first diameter that tapers to a smaller second diameter adjacent an end formation,” as recited in independent claim 1, and similarly recited in independent claims 18 and 21. Applicants submit that the crimps formed in the shown grafts cannot fairly be interpreted as a tubular portion including a generally uniform surface that tapers from a first diameter to a smaller second diameter.

The Office Action alleges that “there is nothing in the language that requires the ‘first diameter portion’ . . . to possess *only one* diameter.” (Office Action, p. 4.) Applicants respectfully disagree. The very language cited by the Office Action provides this requirement. Claims 18 and 21 expressly recites “a first diameter portion.” The phrase “first diameter” is singular. Further, nothing modifies this language to indicate that the diameter is varying, (e.g., “a first diameter portion tapering...”).

Therefore, in view of the above, Applicants respectfully submit that Ehrenfeld does not anticipate independent claims 1, 18, and 21, at least because not all of the claimed features are shown or described thereby. Therefore, independent claims 1, 18, and 21, and claims 2-5, 7-11, 14,

---

<sup>1</sup> See, e.g., *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.* 340 F.3d , 1310-1311 (Fed. Cir. 2003)(which discusses the term “generally parallel”). (See Office Action, p. 4, quoting the definition of “uniform” from Meriam-Webster’s Collegiate Dictionary, 10<sup>th</sup> ed., 1996.)

16, and 19, depending therefrom, are patentable over Ehrenfeld, and Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

Claims 1-5, 7, 14, 16, 18, 19, 21, and 27 stand rejected under 35 U.S.C. § 102(e) as being anticipated by USPN 5,782,916 to Pintauro et al. ("Pintauro"). Applicants respectfully traverse this rejection. The Office Action alleges that Pintauro FIG. 13 illustrates an end formation 114 capable of connection to a blood vessel opening, citing passages in Pintauro that discuss the first anchor 114. Applicants respectfully point out that FIGS. 8-15 provide different views of the same embodiment, referred to in Pintauro as the "alternate embodiment." (Pintauro, col. 6, ll. 65-66.) Accordingly, as shown in FIGS. 8, 9, and 10, which are views of the same embodiment as FIG. 13, Pintauro does not show or describe the features alleged to be disclosed.

Pintauro is directed to a device for maintaining urinary continence, the device inserted in a *nonsurgical* procedure using a cystoscope. (Pintauro, col. 9:8-14.) With respect to the allegation that Pintauro illustrates an end formation capable of connection to a blood vessel opening, Applicants respectfully disagree. The Pintauro device, as clearly shown in FIGS. 1 and 8, has an anchor 114 that extends only *partially* around the end 18, 118 of the tubular body 12, 112. The Office Action admits that "the 'anchor 14 can extend circumferentially up to as much as from approximately 270° to 300°" (Pintauro et al.: column 4, lines 10-11)." (Office Action, p. 5.) Applicants respectfully point out that this means that an at least 60° portion is open.<sup>2</sup> Applicants note that this is more than enough open area to allow a great deal of leakage to occur. Further, the Office Action alleges that "nothing in Applicant's claim 1 and other require the opening to be planer." (Office Action, p. 5.) However, independent claims 1, 18, 21, and 27 each recite a "vascular prosthesis." The Pintauro device would not work as such at least because it would leak due to the large portion missing from the anchor. Accordingly, the Pintauro device is not "configured for surgical connection to an opening formed in a blood vessel" as recited in

---

<sup>2</sup> Applicants also note that the Office Action appears to be combining features from the discussion of the embodiment of FIGS. 1-6 with features from the embodiment FIGS. 8-15.



For the same reason, with respect to independent claim 27, the anchor 14, 114 of Pintauro does not show a second portion with a variable *inner* dimension, or a second portion defining a non-circular *opening*, or an opening defining a cross-sectional *area*. Specifically: 1) without a bounded region, there cannot be an inner dimension, 2) without a bounded region, an opening cannot be defined, and 3) without a bounded region (or an opening), a cross-sectional area cannot be defined (area being generally defined as a quantity expressing the two-dimensional size of a defined part of a surface, typically a region bounded by a closed curve).

Accordingly, Applicants respectfully submit that Pintauro does not anticipate independent claims 1, 18, 21, and 27, because not all of the claimed features are shown or described thereby. Therefore, independent claims 1, 18, 21, and 27, and claims 2-5, 7, 14, 16, and 19, depending therefrom, are patentable over Pintauro, and Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

### **Claim Rejections - 35 U.S.C. § 103**

Claims 6, 15, 17, 20, and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ehrenfeld. Applicants respectfully traverse this rejection. Without conceding the allegations in the Office Action, Applicants submit that claims 6, 15, 17, 20, and 22 depend from a patentable independent claim, in view of the above, and are therefore patentable for at least this reason. Accordingly, Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Claims 6, 15, 17, 20, and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pintauro. Applicants respectfully traverse this rejection. Without conceding the allegations in the Office Action, Applicants submit that claims 6, 15, 17, 20, and 22 depend from a patentable independent claim, in view of the above, and are therefore patentable for at least this reason. Accordingly, Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Claim 27 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over USP/N 4,530,113 to Matterson (“Matterson”). Applicants respectfully traverse this rejection.

The Office Action alleges that forming the shunt 10 of FIG. 6 without the pleats or corrugations 12 would have been an “obvious step backward” in order to simplify manufacture. The Office Action further alleges that the inner arc lengths and diameters along the ends are “variable by virtue of the oblique cut.” (Office Action, p. 3.) Applicants respectfully disagree.

First, as discussed in the previous Response, Matterson teaches to crimp the graft to provide circumferential pleats or corrugations “that help maintain the graft in its open tubular configuration even as it is bent during surgery to accommodate to anatomical requirements.” (Matterson, col. 6:50-54.) Thus, the alleged obvious step backward, instead of being beneficial as suggested, would render the Matterson graft inoperable for its intended purpose, according to Matterson, as the graft would be prone to closing or bending during surgery.

In response to this argument, the Office Action further alleges that “such variants are advantageous economically, in that the crimping step and possibly the heating step . . . are not required.” (Office Action, p. 5.) This does not change the requirements set forth in MPEP § 2143(A), however. “The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art.” (MPEP § 2143(A), emphasis added.) Further, as set forth in MPEP § 2143.01, under KSR, “[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”

Second, even assuming *arguendo* that the “obvious step backward” did not render the Matterson graft inoperable for its intended purpose, there is no disclosure of a “second portion with a variable inner dimension along a second portion of the central axis,” as claimed. The oblique cuts

of the Matterson graft do not change the inner dimension of the graft lumen, and therefore cannot confer to the graft a variable inner dimension along a second portion of the central axis.

In response to this argument, the Office Action further alleges that “[t]he generally elliptical shape created by oblique cut innately involves a continuum of diameters.” (Office Action, p. 5.) However, the variable inner diameter recited in claim 27 is “along a second portion of the central axis.” The oblique cut relied upon in the rejection is inherently *at an angle* with the central axis. Accordingly, even assuming *arguendo* that the Matterson graft at the oblique cuts shows a second and third non-circular opening defining a cross-sectional area that is larger than a cross-sectional area of the first portion of the tube, Matterson does not show a second portion with a variable inner dimension *along a second portion of the central axis*, as claimed.

Accordingly, Applicants respectfully submit that Matterson does not establish a *prima facie* case of obviousness with respect to claim 27, and therefore request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

### **Conclusion**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicants of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Order No. 101675.0070P2 from which the undersigned is authorized to draw.

Dated: November 15, 2010

Respectfully submitted,

Electronic signature: /Todd W. Wight/  
Todd W. Wight  
Registration No.: 45,218  
RUTAN & TUCKER LLP  
611 Anton Boulevard, Suite 1400  
Costa Mesa, California 92626  
(714) 641-5100  
Patents@Rutan.com